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May 7, 1991

Michael Towle
Remedial Project Manager
United States Environmental
Protection Agency
Region III
841 Chestnut Building
Philadelphia, Pa. 19107

Dear Mr. Towle:

We have been reading, with interest, the progress reports and whatever information we receive concerning the C. & D. Superfund Site. From the information available to us, it appears that very little is being accomplished regarding remediation of the site.

Our observation is that the health and welfare of the residents living in that area is not being considered. According to the comments in the Final Draft Remedial Investigation Report prepared by Sharon Rohrbach, it appears there is a lack of concern about the contaminants leaching from the site. This is also evident in reports prepared by the Technical Advisors for the Concerned Citizens of Foster Township Task Force. One would have to be ignorant to believe that the contamination did not leach off site. We agree with Mrs. Rohrbach that contaminants had to leach from the site via wind and water. Why then is the area surrounding the site not being tested? We would also appreciate a list of the known contaminants on the site. We are aware that lead was found at the site. What other hazardous substances were found?

Have former employees of the company been interviewed and health assessments made of them? After all, those who stayed with the company could be considered "dedicated" workers. It is now the company's turn to offer medical attention to those who may have encountered ill effects from the operations conducted at the plant.

COMMENTS ON THE FINAL DRAFT HUMAN HEALTH RISK ASSESSMENT REPORT C&D RECYCLING SITE

By

BARBARA F. BASS, PH.D.

MAY 25, 1991

Prepared For

CLEAN WATER FUND
Washington, D.C.

AND

CONCERNED CITIZENS OF FOSTER TOWNSHIP
Foster Township, Pennsylvania

Prepared Under
USEPA TECHNICAL ASSISTANCE GRANT

General Comments

The overall format of this document follows EPA guidelines as presented in Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A) (RAGS) (EPA/540/1-89/002), but the authors interpretation of the guidance appears to be questionable regarding certain issues. While the authors appear to have responded to some of the commentary made about the "Preliminary Draft" version of the risk assessment (detailed by Henry S. Cole, Ph.D. and John S. Young, Ph.D. in their comments dated June 12, 1990), there are still significant issues that have not been adequately addressed in this "Final Draft". The problems associated with this report are such that the usefulness of the document as an assessment of the risks at the site is debatable. In fact, given the nature of the problems as outlined below, the estimate of the potential risk posed by the site may have been underestimated and, thus, remedial designs based upon this assessment may be inadequate.

Specific Comments

1. Introduction

A. Handling of "Non-detects"

The statement on page 1-2 that assigning a value of 1/2 the CRDL to a sample where a chemical was not detected is "the least acceptable approach" according to EPA guidance is not correct. In fact, this is the recommended approach by EPA in RAGS (EPA, Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), EPA/540/1-89/002, p. 5-10).

B. Estimation of Potential Risks

The authors state (p. 1-2 to 1-3) that the uncertainties associated with the exposure factors recommended by EPA cause an overestimation of potential risk. There is no proof that this is the case. The exposure factors recommended by EPA for use in estimating the reasonable maximum exposure (RME) are values intended to allow an estimation of a "conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures" (EPA, Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), EPA/540/1-89/002, p.6-5). The RME is not intended to be an overestimation of potential risk.

C. Data From Previous Investigations

While it is understandable that the data from previous investigations in which the data were "not accompanied by quality assurance and quality control (QA/QC) information" (p. 1-11) be excluded from use in quantifying the potential risks associated with the site, a discussion of this information should be used in the risk assessment in a qualitative manner. A summary of these

uncertainties associated with exposure concentrations used in the risk assessment:

Off-site - the southern half of the western border of the site (i.e., from the Drasher house south); the eastern half of the northern border; and, the southern border of the site.

On-site - the north eastern section of the site; and, the south central and south western part of the site.

Groundwater Sampling

Given the fact that McLaren/Hart was unable to determine the direction of groundwater flow and given the nature of the hydrogeology in the area, a greater number of monitoring wells placed around the perimeter of the site and within the interior of the site would allow better characterization of groundwater contamination under the site and, thus, decrease the uncertainties associated with the exposure concentrations used in the risk assessment.

C. Air Sampling Conditions

The authors state that the various activities occurring at the site during the air monitoring on November 20, 1989, "could result in disturbance of the Site surface" (p.2-7 and 2-24) and that the air modeling assumed these types of activities were occurring on a continuous basis, thus resulting in a conservative analysis. However, no evidence is given about the extent to which dust was stirred up. Also, given that the monitoring occurred in late November, the results cannot necessarily be assumed to be conservative. If the monitoring had occurred during dry, summer months when dust is more likely to result from such activities, then one might be more likely to assume that the air analysis was conservative from this perspective. Problems associated with the air monitoring data have been raised previously by Dr. Henry S. Cole.

D. Off-Site Groundwater Sampling

There is no discussion of how the off-site groundwater samples were obtained. Therefore, interpretation of the source of a constituent of concern such as lead is difficult. Were the samples taken at the tap? How much flushing of the system was done? Were the samples filtered or unfiltered? The answers to these types of questions impact interpretation of the results and should be presented in the risk assessment.

surficial soil to site-related surficial soil.

In Table 2-10, the assumed off-site background ranges were based upon levels of constituents measured at off-site sampling locations #3, #13, and #36 (p.2-29, footnote #1). These locations are in areas which could have been affected by activities at the site and, therefore, the use of these as representative of background does not appear to be appropriate and departs from EPA guidance as stated above.

Another problem associated with the use of background levels for eliminating chemicals of concern is how the samples of concern were compared to the background samples. Even if one were to accept the background ranges that are presented in the report as valid, the comparison method employed for purposes of this risk assessment is not conservative. One needs at the very least to look at the distribution of concentrations within both the background range and the site-related sample range. It is not inconceivable that all site-related samples could fall within the background range, but have a skewed distribution toward the high end of the range whereas the background samples could be skewed toward the low end of the range. If this were the case, elimination of the constituent from further consideration in the risk assessment would not be justified. However, the approach applied in this risk assessment, i.e., simply eliminating any constituent which had all of its sample concentrations falling within the background range, would not be able to detect these sorts of differences between background and site-related samples and, thus, is not a conservative approach. EPA cites in RAGS several statistical guidance documents that are useful for background comparisons (EPA, Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), EPA/540/1-89/002, p.4-8).

Frequency of Detection:

The authors state that any constituent that was detected in less than 5% of all samples was eliminated. EPA guidance does allow for considering the elimination of a chemical if it is detected infrequently if: "(1) it is detected infrequently in one or perhaps two environmental media, (2) it is not detected in any other sampled media or at high concentrations, and (3) there is no reason to believe that the chemical may be present" (EPA, Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), EPA/540/1-89/002, p.5-22). These considerations were not mentioned in the risk assessment. EPA guidance also indicates that if a detection frequency limit is to be used, it must be approved by the RPM prior to the screening process (EPA, Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), EPA/540/1-89/002, p.5-22). There is no mention of this approval having been received.

on-site area outside the fence from the off-site area and, therefore, ease of access to the on-site area outside the fence does not appear to be any different than access to the off-site area. Thus, "operable units" should not be based on this distinction alone and doing so might result in the potential risk being underestimated.

In forming "operable units" careful consideration should be given to how soil samples are grouped together for purposes of deriving an exposure point concentration. In this assessment, all off-site samples were grouped together. Even if one were to accept the arbitrary distinction made in this assessment between on-site outside the fence and off-site soil samples, grouping all the off-site samples together for purposes of deriving an exposure concentration may have underestimated the potential exposure for those residences most exposed to contaminants from the site.

This assertion is based on the following observations as they relate to lead concentrations in the off-site soil samples: 1) there appears to be a concentration of lead in the off-site samples taken around the northwest quadrant of the site; 2) there are a number of homes near this area (e.g., Drasher) who would more likely be exposed to these soils than soils elsewhere; and, 3) a significant number (approximately 20%) of off-site samples scattered away from the northwest quadrant exhibited no lead concentrations above 200 ppm. A more conservative approach would be to group together the samples around the northwest quadrant and not dilute the overall numbers with those samples exhibiting low lead levels away from this area (e.g., sample #1). This approach would be more realistic for estimating exposures that the families living very near the site (e.g., Drasher) are likely to experience.

Another problem of significant importance involves six off-site soil samples and their exclusion from the group of numbers used to calculate the exposure concentration for residential off-site exposure. A total of 46 off-site soil sample locations were listed in Table 2-3 (p.2-10) and marked on the map in Figure 2-2 (p.2-9). However, only 40 of these were used to calculate the soil concentration to be used for estimating the potential risk for off-site residential exposure. The six samples that were excluded are samples #6, 20, 21, 34, 38, and 40. There is no mention in the text that these six samples were excluded from use in determining soil concentrations for residential exposure nor, needless to say, is there any discussion as to why they were excluded. Upon very close examination of the Appendix B, these six soil samples were found to have been included with the two soil samples (labeled as sediment samples by McLaren/Hart - DS-SED1 and DS-SED2) that were taken to represent the drainage swale on the western side of the site. In the text concerning the drainage swale, there is no mention either about these six off-site soil samples being grouped with the two "sediment" drainage

more conservative approach for assessing residential risk would be to include all eight swale soil samples together with the off-site soil samples.

Another problem with the soil sample concentration estimates involves the issue of soil sampling depth. There were several soil samples taken on-site at a depth of 1 ft and 3 ft. Values for these deeper samples should not be averaged in with the surficial soil samples, but it was unclear whether they were or not. It should also be pointed out whether surficial soil samples were used, i.e., the top 1 to 2 inches, or whether the soil samples represent an average concentration of the top six inches. The potential impact for underestimating exposure when the average value of the top six inches is used should be discussed in detail. This issue has been raised previously by Dr. Henry S. Cole.

Groundwater Samples

The authors group groundwater samples into on-site and off-site operable units. The data within each unit were then averaged together. This is not a conservative approach given that it is likely that upgradient wells are being averaged with downgradient wells. Because the direction of groundwater flow was not determined, it is unknown which wells are upgradient and which are downgradient. This issue has been raised previously by Dr. Henry S. Cole.

In the case of groundwater samples taken from residential wells, one does not need to average these concentrations in order to estimate what residents are potentially being exposed to given that the exposure concentration at the actual point of exposure (i.e., the residence) has been directly measured. A more appropriate approach might be to evaluate the residences on an individual basis. This approach should also be considered for the on-site monitoring wells given the problems with determining the direction of groundwater flow.

I. Handling of "Non-detects"

The authors assert quite often throughout the risk assessment (e.g., p.2-48) that the use of 1/2 the CRQL for non-detects probably overestimates the actual value present. There appears to be no basis for this statement as a blanket assertion. If a constituent is not detected in a sample, one does not know whether the actual value is just below the detection limit or zero. The most conservative assumption would be to assume all non-detects to be equal in value to the CRQL. The least conservative would be to assume the actual value was zero. Assuming 1/2 the CRQL is a semi-conservative approach and may or may not result in an overestimation of the actual value. This issue has been raised previously by Dr. John S. Young.

site, i.e., Mill Hopper Creek, and 4) via inhalation of vapors inside the residence resulting from groundwater contamination. The authors dismiss selection of ingestion of locally grown fruits and vegetables by saying that there are no large-scale agricultural operations in the area (Table 3-2, p.3-28). While this might be the case, it does not address fruits and vegetables grown in the home garden. The exposure pathway involving hunting is dismissed also, but the reasoning is not logical (Table 3-2, p.3-28). Exposure via fish consumption is not considered at all yet fish is apparently taken from Mill Hopper Creek. And exposure to vapors emanating from residential water is not discussed either. These exposure scenarios should be considered. Not doing so may result in the potential risk being underestimated. These considerations have been raised previously by Drs. Henry S. Cole and John S. Young.

C. Exposure Parameters

The various exposure parameters used for calculating potential chronic daily intakes are presented in numerous Tables throughout Chapter 3. The parameters used are suppose to allow the calculation of the reasonable maximum exposure (RME). For example, use of the 95% upper confidence limit value for a particular constituent versus use of the arithmetic mean is utilized in calculating the RME. The following commentary concerns the parameters used in this risk assessment.

Exposure Frequency

The authors throughout the exposure calculations base their exposure frequency values on the fact that the region experiences an average of 165 "frost free" days a year. For example, the authors assume that children in the area ingest outdoor soil only during those "frost free" days. This would not appear to be a conservative assumption. First, during days with frost the ground is not necessarily frozen and soil may be just as available for ingestion on some of these days as during "frost free" days. Second, days with frost may still reach temperatures which would find children playing outdoors with bare hands and thus exposure via ingestion of outdoor soil could occur. A more reasonable maximum estimation of exposure frequency might be to use the number of days per year that the maximum temperature exceeds 45 degrees Fahrenheit.

Exposure Duration

Throughout this report a 30 year exposure duration has been used for adults. According to EPA guidance a 40 year duration might be more appropriate given the rural nature of the area (EPA, Exposure Factors Handbook, EPA/600/8-89/043, Part II, p.1-12). This issue had been raised previously by Dr. John S. Young.

Table 3-28 (p.3-99) On-Site Exposure for Utility Worker

The basis for picking the installation of a utility pole as representative of occupational exposure is not given. Exposures during residential construction and excavation might be a more appropriate scenario for estimating a RME.

D. Uncertainties Analysis

In Tables 3-30 (p.3-105) and 3-31 (p.3-118), the authors assert that for many parameters used to calculate the RME, the result is an overestimation of risk. The basis for their assertion is not clear. In fact, the purpose of using relevant values for estimating the RME is not to overestimate risk, but rather to hopefully ensure that the risk is not underestimated.

4. Toxicity Assessment

A. Lead

Given that there are no current toxicity values (RfD and slope factor) for lead that can be used for quantitating risk, other approaches have been used. The authors discuss current EPA guidance of 500-1000 ppm as a cleanup level. This level is based upon a Centers for Disease Control (CDC) recommendation which states that levels of lead in soil exceeding 500-1000 ppm appear to be associated with increasing blood lead levels in children above background. This recommendation was published in 1985 and since that time further work has been done not only on the levels of blood lead associated with toxic effects, but also on the levels of soil lead exposure associated with blood lead levels.

Not discussed in the text of the risk assessment, but presented in Appendix E.2 is EPA's ECAO's current recommendation of 300 ppm if soil cleanup is driven by direct soil contact. ECAO also has stated that at a concentration of 200 ppm of lead in soil, the lead is not bioavailable. These views of ECAO should be openly discussed in the text of the risk assessment and not be tucked away in the Appendix.

McLaren/Hart at the request of EPA Region III employed the Lead Uptake/Biokinetic Model to assess risks to children at the site. While the model apparently continues to undergo revisions, it has been distributed to the Regions for their use. There is little description of the model in the risk assessment. A longer and more detailed explanation of how it works would be appropriate.

B. Dermal Exposure to PAHs

The authors state that laboratory research indicating that PAHs are associated with skin cancer occurred under conditions not comparable to those at the site, thereby, implying that dermal

authors are referred to the EPA's Drinking Water Health Advisories that calculate separate assessments for adults and children even when there is not a significant difference in toxic effects between the two populations. If children are not any more sensitive to a toxic substance than an adult, they may still experience more risk than an adult. The important parameter is dose, i.e., amount to which one is exposed per unit of body weight. Clearly, under some circumstances children may receive a higher dose than adults based upon their intake rate and their body weight.

D. Combining Carcinogenic Risks Across Ages 0-30

The position taken by the authors that combining carcinogenic risks across ages is not valid (Section 5.3.5, p.5-48) is incorrect if one considers the toxicological principles upon which risk assessment is based. This might not be an approach that is routinely used, but that does not make it an invalid one. (See above discussion above concerning assessing risks to children.

E. Binary Carcinogen Interactive Data Base

The authors indicate that few relevant studies were found in the search of this data base; some indicated additive effects, others antagonistic effects. From this the authors conclude that there are no significant additive effects between parameters at the site. However, it would appear that the paucity of relevant data supports instead the position that not enough data were available to determine whether or not significant additive effects could be expected given constituents at the site.

F. Lead in Soil

The discussion in Section 5.4.2.1.1.3 (p.5-67) should clearly discuss ECAO's position on soil lead levels (see above discussion in 4.A).

Another issue that needs discussion and clarification has to do with the results of the Lead Uptake/Biokinetic Model. Using a soil lead concentration of 476.6 ppm as well as including exposures to other sources of lead, the model predicted under the worst case scenario used that approximately 6% of exposed children ages 0-6 years would be expected to have blood lead levels equal to or greater than 10 ug/dL. However, ECAO indicates that at a soil lead concentration of 500 ppm and with no additional sources of lead exposure approximately 33% of children under 2 years of age would have blood lead levels of 15 ug/dL (Appendix E.2). This apparent contradiction in findings needs to be explained.

CLEAN WATER FUND

March 25, 1991

Mr. Mike Towle
Remedial Project Manager
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Region III, U. S. EPA
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Dear Mr. Towle:

Please find attached a detailed review of the Final Human Health Risk Assessment Report, C & D Recycling Site written by Clean Water Fund's subcontractor, Dr. Barbara Bass. As noted in these comments, many of Dr. Bass's concerns are the same concerns that Drs. Cole and Young have raised in our comments of June 1990. Many serious problems have still not been addressed.

Moreover, As is apparent from the comments of Dr. Bass it is apparent that the RA still contains numerous instances of questionable judgement and assumptions. Collectively these problems may lead to significant understatement of the risks posed to people living in the vicinity of the site. For this reason, EPA should not attempt to use the document in its present form to make judgements about risk or remedy selection.

Secondly, I have reviewed the section on Air (2.2.5) and was surprised to see that the comments we made in June 1990 were totally disregarded. The problems stand:

Hart Associates have not demonstrated that November 27, 1987 is really a worst case condition for particulate emission rates for the site (used in modelling to support the risk assessment):

o Such terms as "erosion control work" are vague and may have little relationship to soil disturbance or release of particles, specifically from parts of the site that are highly contaminated.

o The emission estimates are based on 2 downwind monitors which may not have experienced maximum concentrations associated with soil particles.

o No information was given on soil conditions at the time of monitoring; if soils were damp, snow covered or frozen, or if it was raining at the time, release of soil particles would have been retarded.

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